IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INNOVATIVE THERAPIES, INC., Plaintiff, v. KINETIC CONCEPTS, INC., KCI LICENSING, INC. and KCI USA, INC. Defendants.	C.A. No. 1:07-cv-589-SLR **DECLARATION OF DAVID M. TUMEY**

DECLARATION OF DAVID M. TUMEY

1. I am an officer of Innovative Therapies, Inc. ("ITI"), and currently serve as its Chief Technology Officer.

2. I was employed by Kinetic Concepts, Inc. ("KCI") from 1996 to 2004.

3. For five years of my employment with KCI, I acted as Director of Research and Development, during which time I managed development of the Vacuum Assisted Closure ("V.A.C.") wound therapy product line.

4. As Director of Research and Development for the V.A.C. product line, I assisted KCI's litigation counsel in the Blue Sky litigation by acquiring competitive products and analyzing them through reverse engineering and other tests. My team provided KCI's litigation counsel with various reports of the results of the analyses. Based on my experiences, I am aware of KCI's policy of aggressively enforcing its patent rights.

5. I believed that the introduction of ITI's Svedman Wound Treatment System ("Svedman") to the market, as a competitor to KCI's V.A.C. product line, would expose ITI to a high risk of litigation based on my experience with KCI's patent enforcement policy and aggressive history of suits against competitors and even hospitals and doctors.

6. On September 12, 2007, I called Michael Girouard, KCI's Director of Marketing and a former co-worker of mine at KCI. ITI's Mark Meents also participated in the call. The purpose of the call was to assess the risk of litigation to which ITI would be exposed and to gauge the possibility of establishing a business relationship between ITI and KCI.

7. I believed that, as a KCI Director, Mr. Girouard would be in a position to understand KCI's current institutional attitude toward patent enforcement against competitive products.

8. After catching up for several minutes, I asked Mr. Girouard if he was aware of the two recently approved 510(k)s that we had submitted. Mr. Girouard replied that he was aware of one, but not two of the 510(k)s.

9. Attached at Exhibit A are the summaries and clearances (the Food and Drug Administration's ("FDA's") term for approvals) for both 510(k)s submitted by ITI. These documents are publicly available at the FDA website http://www.fda.gov. My name is included as the "Contact Person" on the 510(k) for the ANTLIA II Suction Pump System.

10. I have read the portion of the Declaration of Michael Girouard filed by KCI in this case in which he states that, "I was not aware of Mr. Tumey's two 510(k)s or his product before our conversation." To the extent that Mr. Girouard meant to indicate that he was not aware of ***both*** 510(k)s, this statement is accurate. Alternatively, if Mr. Girouard meant to indicate that he was not aware of either 510(k), this statement is contrary to his response during the September 12, 2007 phone call, as evidenced by the typed notes that I prepared following the call, attached as Exhibit B.

11. Mr. Girouard further noted that his awareness of one of the 510(k)s came from KCI's regular "Competitive Intelligence" meetings, which I gathered to be formal meetings in which members of the marketing department discuss competitor activities and their products.

12. I then explained to Mr. Girouard that we had been developing and were considering

launching a wound healing system that utilized negative pressure and a polyurethane foam dressing. Following this description of the Svedman, I asked Mr. Girouard how he thought KCI might react. As reflected in my handwritten contemporaneous notes of the call attached as Exhibit C, Mr. Girouard responded: "KCI will act aggressively. You know that."

13. When I asked Mr. Girouard whether this meant that KCI would sue if we launched this product, he responded that KCI would take legal action, but clearly indicated that such action would take place only after KCI determined that the product infringed the KCI patents.

14. I have no recollection of Mr. Girouard telling me, as he states in his declaration, that he "did not know whether KCI would take any action." Nor do I recall Mr. Girouard stating that "this would not be my determination in any event." Furthermore, these comments are not reflected in my contemporaneous notes of the call, attached as Exhibit C, or in my subsequently prepared typed notes, attached as Exhibit B.

15. On September 17, 2007, I called Michael Burke, KCI's Senior Vice President of Manufacturing, a member of KCI's Executive Committee, and my former supervisor. As with the call to Mr. Girouard, the purpose was to determine ITI's degree of risk in launching the Svedman and to explore a potential business relationship between ITI and KCI.

16. I believed that, as an Executive Committee member and Senior Vice President of the company, Mr. Burke would be able to provide a realistic assessment of the KCI mind-set regarding enforcement of its patents against competitive products.

17. I took down handwritten contemporaneous notes of the conversation (a copy of which is attached as Exhibit D) and later that same day I typed up a summary of the call (a copy of which is attached as Exhibit E).

18. After several minutes of small talk, I asked for Mr. Burke's advice regarding the launch of the Svedman. After describing the product as a negative pressure wound healing system utilizing

a polyurethane foam dressing, I asked Mr. Burke how he thought KCI would react to the release of such a product. As reflected in my handwritten contemporaneous notes, Mr. Burke replied that KCI would "aggressively go after us" "particularly if it is foam-based."

19. Following up on Mr. Burke's comments, I next asked him what were the odds that ITI would be sued by KCI. Mr. Burke told me that the odds were very big. Looking for clarification, I asked, "100%?" As reflected in my handwritten contemporaneous notes, Mr. Burke replied that the odds were "100% no doubt about it." He clarified this point by adding that any product that "scratches the surface of our patents" would be the subject of a lawsuit.

20. I next attempted to explore the possibility of a mutually beneficial relationship by asking whether there was any way that KCI and ITI could peacefully coexist. As reflected in my handwritten contemporaneous notes, Mr. Burke quickly dismissed the possibility, replying that there was "no way to coexist" and that it would not happen.

21. Mr. Burke concluded by advising me to steer clear of a negative pressure wound therapy device that is foam-based: "I would steer clear of npwt + foam-based." This statement is reflected in my handwritten contemporaneous notes.

22. I have read the portion of the Declaration of Michael Burke filed by KCI in this case in which he states that, "I told Mr. Tumey that I was in no position to speak for KCI" and that "I was not in the loop." These statements are not true. Mr. Burke's comments described how he expected KCI to react to the release of a negative pressure, foam dressing wound healing system. Mr. Burke never once, let alone repeatedly, stated that he was "not in the loop." Nor did Mr. Burke at any time in the conversation make any equivalent statements suggesting that he had any doubts that KCI would act in the manner that he described.

23. Based on my conversations with Mr. Girouard and Mr. Burke, my own previous experience dealing with KCI's patents and patent attorneys as a Director at KCI, and KCI's

history of asserting patent infringement claims against every competitor that has launched a commercially viable negative pressure wound therapy device on the market, I believed that KCI would definitely sue ITI for patent infringement if ITI introduced the Svedman.

24. The facts set forth above are true and complete to the best of my knowledge and recollection.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on this 13th day of November, 2007.

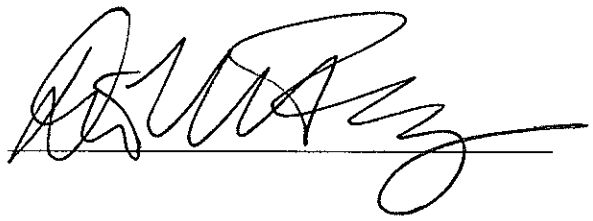

Exhibit A

K071301

510(k) Summary

MAY 24 2007

ANTLIA I™ WOUND IRRIGATION SYSTEM

1.	**Name/Address of Submitter:**	**Innovative Therapies, Inc.** **10948 Beaver Dam Road, Suite C** **Hunt Valley, MD 21030**
2.	**Contact Person:**	**Judith Harbour** **Phone: 866-200-0412** **e-mail: jharbour@charter.com**
3.	**Date Summary Prepared:**	**May 4, 2007**
4.	**Name of Device:**	**ANTLIA I™ Wound Irrigation System**
5.	**Classification Name:**	**Powered Suction Pump** **21 CFR 878.4780** **Class II**
6.	**Predicate Device:**	**V.A.C.® Instill™** **510(k) No.K021501**

7. **Description of Device**

The ANTLIA I™ Wound Irrigation System is an AC-powered, portable suction device with battery back-up that provides vacuum assisted drainage and irrigation of a wound site by controlled delivery of topical wound treatment solutions over the wound bed.

The specifically designed Aquarius I™ dressing components are provided for irrigation to a wound with sterile saline or other applicable topical solutions. During and after irrigation, negative pressure can be applied to assist in the removal of infectious materials or other fluids.

8. **Indication For Use**

The ANTLIA I™ Wound Irrigation System device is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

The ANTLIA I™ Wound Irrigation System is intended for patients with chronic, acute, traumatic, subacute, and dehisced wounds, diabetic ulcers, pressure ulcers, flaps and grafts.

9. Technological Characteristics and Substantial Equivalence

The ANTLIA I™ Wound Irrigation Therapy Unit has essentially the same technological characteristics as the previously cleared predicate device and has been independently tested and successfully approved to the following medical safety standards:

- IEC 60601-1 + US deviations (UL60601-1), Medical Electrical Equipment– Part1:General Requirements for Safety; 1. Collateral Standard: Safety Requirements for Medical electrical Systems
- EN 60601-1-2: 2001 version (2nd Edition), Medical Electrical Equipment – Part 1-2: General Requirements for Safety–2. Collateral Standard: Electromagnetic Compatibility Requirements and Tests
- IEC 60601-1-4, Medical Electrical Equipment – Part 1: General Requirements for Safety -4.Collateral Standard: Programmable Electrical Medical Systems

10. Conclusion

The substantial equivalence for the ANTLIA I™ Wound Irrigation System is based on the same indications, intended use, and technological features of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2007

Innovative Therapies, Inc.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K071301
Trade/Device Name: ANTLIA 1™ Wound Irrigation System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA
Dated: May 8, 2007
Received: May 9, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071301

Device Name: ANTLIA 1™ Wound Irrigation System

Indications For Use:

The ANTLIA 1™ Wound Irrigation System device is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

The ANTLIA 1™ Wound Irrigation System is intended for patients with chronic, acute, traumatic, subacute, and dehisced wounds, diabetic ulcers, pressure ulcers, flaps and grafts.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Prescription Use ___v___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Page 1 of 1

510(k) Number K071301

K070904

510(k) Summary

ANTLIA II™ SUCTION PUMP SYSTEM

APR 13 2007

1. **Name/Address of Submitter:** **Innovative Therapies, Inc.**
10948 Beaver Dam Road, Suite C
Hunt Valley, MD 21030

2. **Contact Person:** **Dave Tumey**

3. **Date Summary Prepared:** **March 16, 2007**

4. **Name of Device:** **ANTLIA II™ Suction Pump System**

5. **Classification Name:** **Powered Suction Pump**
21 CFR 878.4780
Class II

6. **Predicate Device:** **Medela Invia™ Healing System, K061435**
BlueSky Medical Versatile 1™ Wound Vacuum System, K052456

7. **Description of Device**

The ANTLIA II™ Suction Pump System, an AC-powered, portable suction device with battery back-up, provides localized negative pressure when used with the Aquarius II™ dressing to remove fluids and infectious materials from the wound to promote wound healing. It is intended for use on patients who would benefit from a suction device, particularly as the device may promote wound healing, including patients who would benefit from vacuum assisted drainage and removal of infectious material, irrigation fluids or other body fluids from wounds.

The system consists of a powered suction pump device with a built-in placement holder for a fluid collection canister, the Aquarius II ™ polyurethane foam dressing, and canister tubing with clamps and connectors, and two polyurethane drapes with adhesive.

8. **Indication for Use**
The ANTLIA II™ Suction Pump System is indicated for the application of suction (negative pressure) to wounds to promote wound healing and for the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials.

9. Technological Characteristics and Substantial Equivalence

The ANTLIA II™ Suction Pump Therapy Unit has the same technological characteristics as the predicate's powered suction pump. The individual dressing components consists of materials that are either identical or substantially equivalent to the predicate's dressing components.

10. Conclusion

The substantial equivalence for the ANTLIA II™ Suction Pump System is based on the same indications, intended use, and technological features of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Innovative Therapies, Inc.
% Regulatory Technology Services LLC
Mr. Mark Job
1394 25th Street Northwest
Buffalo, Minnesota 55313

APR 13 2007

Re: K070904
Trade/Device Name: ANTLIA II™ Suction Pump System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA
Dated: March 30, 2007
Received: April 2, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070904

Device Name: ANTLIA II™ Suction Pump System

Indications For Use:

The ANTLIA II™ Suction Pump System is indicated for the application of suction (negative pressure) to wounds to promote wound healing and for the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070904

Prescription Use ___v___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Exhibit B

Recordation of the 9/12/07 12:21 PM telephone call with Mike Girouard:

On the call were Dave Tumey, Mark Meents and Mike Girouard. Mark and Dave were together by speakerphone, Mike was at KCI on his cell phone.

The call began with an exchange of pleasantries. We spent a minute or two catching up and discussed some recent personnel departures and additions at KCI.

I then asked Mike if I could "run something by him". I asked if he was aware of the 510(k)'s we recently received and he indicated he was "aware of one but not two". I told Mike that Mark and I have been working on developing a new product. I described our product to him, namely that it was a wound healing system that utilized negative pressure in the range of 75 to 150 mmHg, and a dressing made of polyurethane foam – not gauze. I explained that we were thinking of launching this product and I asked "how do you think KCI is going to take this?"

He replied "KCI will act aggressively. You know that."

I then asked if we were at risk here, did we need to be concerned about potential litigation?

He replied "Post analysis, if KCI feels your product infringes their patents, they would have to take legal action."

Lastly, I asked if it was KCI's position that they "owned negative pressure and foam?" to which Mike replied "KCI will protect its IP. If you don't defend your patents you will lose them."

Mark and I said our goodbyes at this point and the call was terminated. The time was approximately 12:35 PM.

Exhibit C

9/12/07 Mike Girouard

12:21 pm Phone conversation

On call: D. Tumey, M. Meents

Call: M. Girouard (@ KCI)

- Exchanged pleasantries, spent a few minutes catching up

- Described product & asked "How will KCI react"?

* "KCI will act aggressively. You know that!"

- Asked if we are @ risk (for lit.)?

* "Post Appl, if K feels that we infringe their patents, they would have 2 take legal action"

- Does KCI own input + Foam?

* "KCI will protect its ip"
"If U don't defend you will lose them."
^ our patents.

call ended @ ~ 12:35 p.m.

Exhibit D

9/17/07 3:21 p.m.

CALL TO MIKE BURKE w/ DAVE TUMEY.

Spent 1-2 min catching up (last 2-years (family + school)) on way to Mexico

Explained product → NP + FOAM.

How will ICI react?

"ICI will aggressively go after us. Particularly if it is foam-based."

New patents, 2 will extend.

What are the odds we will be sued?

ODDS.

Will we be sued?? "Very big 100% no doubt about it."

"Aydin not scratch the surface of our patents we go after them."

Any way to peacefully co-exist?

"No way to co-exist will not happen."

"Invented/started closed cell foam + foam-based."

Not aware of stock's.

Needed sanity check!

Bye + say hi to Janice.

3:27 Ended.

Exhibit E

Recordation of the 9/17/07 3:21 PM (E.T.) telephone call with Mike Burke:

On the call were Dave Tumey, and Mike Burke. Mike was on his cell phone traveling to Mexico for business.

We spent one or two minutes catching up on the last 3 years, I told Mike about flying and school for the two years after leaving KCI. I congratulated him on his retirement at the end of the month.

I asked Mike if I could "get some advice from him". I explained that after the expiration of my non-compete agreement, I began working on a project that is nearing launch. I described the product telling him it was a wound healing system that used negative pressure and a polyurethane foam dressing as a component and asked him: "How do you think KCI would react if we launch this product?"

He replied "KCI will aggressively go after you, particularly if it is foam-based"

He indicated that KCI has recently received some new patents that would "extend" the life of the patents (I was not sure what he meant by this).

I then asked him "What are the odds we will be sued?"

He replied "Very Big, 100%, no doubt about it."
He added: "Anything that scratches the surface of our patents we will go after them."

I then asked him if there was any way to peacefully co-exist?

Mike replied: "No way to co-exist, it will not happen."
He then stated that: "I would steer clear of negative pressure and foam-based."

I asked Mike if he was aware of our 510(k)'s and he told me he was not. I told him that I agreed with his assessment and I thanked him for the "Sanity Check" and his advice.

We then said our goodbyes and the call was terminated at approximately 3:27 PM (ET).

CERTIFICATE OF SERVICE

I hereby certify that on April 4, 2008, a copy of the foregoing Declaration of David Tumey was served with the Clerk of the Court using CM/ECF, which will send automatic notification of the filing to the following

Steven J. Balick, Esq.
John G. Day, Esq.
Tiffany Geyer Lydon, Esq.
Ashby & Geddes
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899

In addition, the forgoing was also served via e-mail upon:

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Don O. Burley, Esq.
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/s/ Thomas H. Kovach
Thomas H. Kovach (#3964)